

17. VACCINE LOSS AND REPLACEMENT

Providers may be required to:

- Replace vaccine lost due to negligence, non-compliance, fraud, or abuse
- Incur the cost of re-vaccination due to negligence.

Requirement

Providers must consult with the Immunization Program before making determinations about vaccine viability following a temperature excursion.

Situations That May Require Vaccine Replacement

Provider Negligence

Listed below are situation considered to be “provider negligence” and may require vaccine replacement if they result in vaccine loss. This list is not exhaustive. Failure of a provider or staff to adhere to any provision of the current *Montana VFC Handbook/Vaccine Management Plan* may result in a replacement situation. Situations not listed here will be considered on an individual basis by the Immunization Program.

- Failing to log temperatures twice daily during normal operating hours
- Failing to properly install and manage State-supplied Data Loggers or otherwise compliant thermometers (See Section 14 – Thermometer Policy)
- Falsely certifying cold chain documentation in imMTrax
- Failing to notify the Immunization Program of a change in VFC vaccine management personnel (Vaccine Manager and Alternate VFC Vaccine Manger)
- Preparing vaccine for administration prior to patient screening
- Storing VFC vaccine in prohibited storage units
- Storing VFC vaccine in a storage unit that has not been approved by the Immunization Program.
- Failing to receive and properly store vaccine delivered during designated delivery hours
- Failing to take action to protect vaccine after becoming aware of out-of-range temperatures, equipment malfunctions, or electrical supply issues
- Storing vaccine at improper temperatures (e.g., leaving vaccine at room temperature, storing frozen vaccine in the refrigerator or refrigerated vaccine in the freezer)
- Staff, maintenance workers, or contractors purposefully interrupting storage unit electrical supply without taking action to protect vaccine
- Leaving a storage unit door ajar
- Failing to contact the MSCC (1-877-836-7123) the same day an order arrives at your facility when you suspect it was compromised during shipment
- Failing to provide proof of repair or replacement within 30 days of discovering a storage unit equipment failure
- During a power outage, failing to protect vaccine according to the posted emergency plan when it is safe and possible to do so

Provider Fraud and Abuse

VFC providers are required to replace vaccine lost due to substantiated instances of program fraud and abuse. See Section 9 – Non-compliance, Fraud, and Abuse for more information.

Situations That Do Not Require Vaccine Replacement

Listed below are situations where providers are deemed not at fault and that are not considered “provider negligence.” This list is not exhaustive. Providers may be required to produce a letter from the power company or alarm company.

- Vaccine shipments not delivered in a timely manner, delivered outside designated delivery hours, or otherwise damaged or stored improperly during transit and where the provider called the MSCC (1-877-836-7123) as soon as the incident was discovered.
- A contracted alarm/alert company failing to notify the provider of malfunctioning equipment or out-of-range temperatures as required
- A provider following their emergency plan in response to a power failure, but their alternate location is inaccessible or without power
- Provider prevented from following their emergency plan due to safety or access issues
- Vaccine accidentally broken or dropped
- Vaccine prepared for administration after patient screening but not administered due to parental refusal or a change in physician orders
- Refrigerator/freezer equipment problems where proof of repair or equipment replacement is provided to the Immunization Program within 30 days from the date of discovery
- Extraordinary situations not listed above that are deemed by the Immunization Program to be beyond the provider’s control.

Procedures for Vaccine Replacement

- The Immunization Program considers the evidence surrounding each situation when determining whether vaccine must be replaced. The evidence includes but is not limited to provider communications, Immunization Program staff observations, data logger data, Vaccine Incident Reports, provider temperature logs, imMTrax cold chain data, wasted and expired forms, imMTrax inventory records, eligibility screening documents/data, and borrowing reports.
- If replacement is required, the Immunization Program will notify the provider in writing including the vaccine, number of doses, monetary value, and reason restitution is requested.

Providers must reimburse public vaccine dose-for-dose with vaccine from private stock. Monetary payment directly to the Immunization Program is not allowed. Within 90 days, providers must report the replaced doses on a Vaccine Restitution Report and may be required to provide copies of purchase invoices.

